

UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO
EASTERN DIVISION

INTERNATIONAL DAIRY FOODS
ASSOCIATION

and

ORGANIC TRADE ASSOCIATION

Plaintiffs,

v.

ROBERT J. BOGGS
(solely in his official capacity as Ohio Director
of Agriculture)

Defendant.

CASE NO.: 2:08-CV-628, 629

Judge: Graham

ORAL ARGUMENT REQUESTED

SEPARATE STATEMENT OF UNDISPUTED FACTS

1. Plaintiff, International Dairy Foods Association (“IDFA”) is a trade association whose members together represent more than 85% of the milk, cultured products, cheese and frozen desserts produced and marketed in the United States. IDFA’s members market many of the dairy products sold in Ohio. IDFA App. in Supp. of Prelim. Inj. (“P.I. App.”) 0421, ¶ C; P.I. App. 0428, ¶ 8; P.I. App. 0433-34, ¶¶ 3-4; P.I. App. 0451, ¶¶ 5-7; P.I. App. 0461, ¶ 4.
2. Many of the products IDFA’s members sell are produced from milk received from farmers who pledge not to treat their cows with recombinant bovine growth hormone (“rbGH”) also known as recombinant bovine somatotropin (“rbST”), a genetically engineered hormone administered to lactating dairy cows to increase their milk production. *Id.*
3. Plaintiff, Organic Trade Association (“OTA”), is a membership-based business association for the organic industry in North America. OTA’s mission is to promote and protect organic trade. OTA represents businesses across the organic supply chain and addresses all

things organic, including food, fiber/textiles, personal care products, and new sectors as they develop. Plaintiff's members include many of the companies selling organic dairy products in the State of Ohio. Organic Trade Association's Addendum of Evidence in Support of Motion for Summary Judgment ("OTA Add."), Ex. E ¶ 2.

4. OTA has hundreds of members which include numerous organic dairy processors who market and sell their products in Ohio including HORIZON ORGANIC© and Stonyfield Farm, Inc. OTA's members include most of the companies selling organic dairy products in the State of Ohio. OTA Add., Ex. 2 ¶ 3.

5. Defendant Robert J. Boggs is the Ohio Director of Agriculture.

CONSUMER DEMAND

6. Many consumers oppose the use of the genetically engineered hormone rbGH. Some consumers believe that administering supplemental amounts of growth hormones to lactating dairy cows amounts to poor animal husbandry. Others are just opposed to the use of genetic engineering in the production of food. P.I. App. 0421, ¶ C; P.I. App. 0428, ¶ 8; P.I. App. 0434, ¶ 4; P.I. App. 0452, ¶ 7; P.I. App. 0461, ¶ 4; S.J. App.II 0483, ¶ 3; S.J. App.II 0487, ¶3; S.J. App.II 0489, ¶ 3; S.J. App.II 0491, ¶ 3; S.J. App.II 0493, Decl. ¶ 3; S.J. App.II, ¶ 3; S.J. App.II 0497-98, ¶¶ 3-5; S.J. App.II 0501-02, ¶¶ 3-5; S.J. App.II 0504-06, ¶¶ 3-5; OTA Add., Ex. A ¶ 14; OTA Add. Ex. B ¶¶ 14-17; OTA Add. Ex. C ¶¶ 14-15; OTA Add., Ex. F.

7. In 2006 the United States Department of Agriculture ("USDA") commissioned a survey to gauge consumer interest and concern over the use of growth hormones in dairy products. That survey indicated that consumers want to know which dairy products contain milk from cows treated with rbGH and which do not. OTA Add., Ex. A ¶ 14; OTA Add., Ex. F.

8. As a result of consumer demand, many of IDFA's members have decided that they will not accept milk from their suppliers that comes from cows that have been treated with rbGH.

These IDFA members have entered into agreements with their suppliers to ensure that the milk they receive does not come from treated cows. In some cases, IDFA members have agreed to pay farmers a monetary premium to compensate them for participating in these agreements. P.I. App. 0427-28, ¶¶ 3-4, 7; P.I. App. 0434, ¶ 4; P.I. App. 0443, ¶ 3.3; P.I. App. 0451, ¶ 5.

9. OTA's members who are certified to sell organic dairy products must not use milk from cows treated with rbGH in any product labeled as organic. OTA Add., Ex. B ¶¶ 14-17, OTA Add., Ex. C ¶¶ 14-15.

10. Many OTA members and IDFA members voluntarily label their products with messages to indicate that the milk or cream used in a particular dairy product is supplied by farmers who have not treated their dairy cows with rbGH. P.I. App. 0421, ¶ D; P.I. App. 0434, ¶¶ 5-6; P.I. App. 0443, ¶¶ 4.1-4.2; P.I. App. 0452, ¶ 8; P.I. App. 0462, ¶ 6; OTA Add., Ex. A ¶ 17; OTA Add., Ex. B ¶ 29; OTA Add., Ex. C ¶ 16.

FACTS ABOUT RBGH

11. On November 5, 1993, the United States Food and Drug Administration ("FDA") approved the animal drug application from the Monsanto Company for rbGH (POSILAC®). The FDA relied on a study by the Animal Sciences Division of Monsanto, which concluded that rbGH would be safe and effective for dairy cows, that milk from rbGH-treated cows would be safe for human consumption, and that production and use of rbGH would not have a significant impact on the environment. S.J. App.II 0478-82.

12. Lactating dairy cows naturally produce their own supply of bovine growth hormone ("bGH"), but when these cows are given injections of rbGH, the synthetic hormone combines with the naturally occurring bGH to permit an increase in the cows' milk production by up to ten percent. P.I. App. 0001-02; OTA Add., Ex. 1 ¶ 12; OTA Add., Ex. B ¶ 12; OTA Add., Ex. C ¶ 12; OTA Add., Ex. D ¶ 4.

FDA AND OTHER STATE LABELING POLICY REGARDING rbGH

13. When rbGH was approved for use, the FDA declined to require special labeling for milk derived from cows treated with the drug. In response to state, industry and consumer requests, the FDA in February 1994 issued interim guidance on the voluntary labeling of milk and milk products derived from cows not treated with rbGH. (“FDA Guidance”). That guidance provides a “Safe Harbor” for dairy processors and manufacturers, which states that food companies can voluntarily inform consumers via product labels that the dairy product was manufactured using milk from cows that were not treated with rbGH, provided such statements are truthful and not misleading. 59 Fed. Reg. 6279-80 (Feb. 10, 1994); P.I. App. 0001-02.

14. In adopting the guidance, the FDA’s key concern was avoiding the potentially misleading implication that milk derived from cows not treated with rbGH is safer or of higher quality than milk from cows treated with rbGH. With that concern in mind, the FDA issued interim guidance providing that rbGH non-use claims “may be potentially misleading,” and thus, a contextual statement could help dispel any misleading implications. FDA provided an example of an acceptable contextual statement as: “No significant difference has been shown between milk derived from rbST-treated and non-rbST-treated cows.” 59 Fed. Reg. 6279-80 (Feb. 10, 1994); P.I. App. 0001-02. However, FDA has expressly stated that the proposed contextual language or even any contextual language is not necessary or mandatory: “that in many instances a statement like ‘from cows not treated with rbST’ would not be misleading, and in no instance is the specific statement ‘No significant difference . . .’ required by FDA.” P.I. App. 0003-04.

15. As an industry standard, dairy companies use the FDA Guidance as a starting point for designing their labels and often design labels to conform to the FDA Guidance. P.I. App. 0428.

16. FDA has reaffirmed the appropriateness of the Safe Harbor several times since its initial adoption, and as recently as June 2007, declined a request to revisit the 1994 guidance. P.I. App. 0093.

17. For example, Monsanto requested that the FDA or the Federal Trade Commission (“FTC”) limit the use of rbGH labels or to find that labels in the marketplace are misleading. P.I. App. 0093; P.I. App. 0094-96. In August 2007, the FTC declined Monsanto’s request to undertake a formal enforcement action for misleading advertising relating to rbGH on the basis that except for a few instances, the advertisements were consistent with FDA guidance and not deceptive. P.I. App. 0094-96.

18. Pennsylvania issued guidance that expressly provides on its face for the opportunity to seek approval of a dairy product label that has been approved by another state jurisdiction even if the label does not otherwise comply with Pennsylvania’s guidance. Pennsylvania permits phrases such as “No rbGH,” if accompanied by the “our farmers pledge no use of” language. Pennsylvania does not dictate the color of the contextual language. P.I. App. 0413-18. The Shamrock label has been submitted for approval pursuant to that provision. P.I. App. 0422, ¶ G.

19. Illinois adopted a Technical Bulletin after some members of commercial industry sued Illinois over its non-use label ban. App. P.I. 0397-0401. Notwithstanding the Technical Bulletin’s position that “rbST Free” claims will not be permitted, Illinois permits Shamrock’s “No rbST – our cows are not treated with the growth hormone rbST” label. P.I. App. 0421, ¶ F.

OHIO’S ADOPTION OF NEW LABELING REGULATIONS

20. Dairy products have been sold in Ohio with non-rbGH use labels since at least 1997. P.I. App. 0443, ¶ 4.1.

21. Ohio processors requested that, effective February 2008 dairy farmers supply them only with milk from cows not treated with rbGH. P.I. App. 0433-34.

22. The Advisory Committee held meetings on December 6, 2007 and December 19, 2007 for the purpose of receiving comments and suggestions from interested parties to aid the Director in establishing a policy regarding dairy labeling. S.J. App.II 0512-13. The only consumer identified on the twenty-person Advisory Committee was Robin Steiner. S.J. App.II 0514. Robin Steiner (as of July 21, 2008) is listed on a Monsanto website as an Area Market Manager Representative for POSILAC®. S.J. App.II 0515-18. She also currently resides at the same address as a dairy farmer who commented in favor of the rule. S.J. App.II 0519-21.

23. After these meetings, on or about February 7, 2008, the Director issued an Emergency Rule regarding dairy product labeling that, for the first time in Ohio, singled out rbGH for specific rules and restrictions that forbid certain kinds of claims on milk labels, mandated the FDA disclaimer language and imposed rules on the placement, size and location of the FDA disclaimer language. P.I. App. 0099-104 (“Emergency Rule”).

24. In or about November, 2007, the Director of the Ohio Department of Agriculture (“Director”) formed an Ohio Dairy Labeling Advisory Committee (“Advisory Committee”).

25. Prior to the adoption of the Emergency Rule, representatives from Monsanto contacted and corresponded with the Ohio Department of Agriculture (“ODA”) about the issue of rbGH non-use labels, as far back as May 2007. A selection of those correspondences can be found at S.J. App.II 0522-44. These documents were not included as a part of the record underlying enactment of the Emergency Rule; rather they were received from ODA in response to a request for emails to and from Monsanto.

26. Also prior to the enactment of the Emergency Rule, ODA did not have any record of consumer complaints regarding existing labeling of milk products, nor did ODA undertake any enforcement actions against companies challenging their existing labels. In a letter dated July 6, 2008, IDFA requested documents from ODA including “any records of enforcement actions

taken by ODA regarding milk labels from 1994 to the present” and “all consumer complaints regarding dairy products and rbST from 1994 to the present.” S.J. App.II 0510. Of the numerous documents ODA provided in response, not one was an enforcement action by ODA or a consumer complaint.

27. The Governor of Ohio issued Executive Order 2008-03S, supporting the Emergency Rule. The Governor of Ohio stated that the Director should exercise his labeling authority “in a manner which maximizes consumer information, and thus, consumer choice.” P.I. App. 102. The Governor also acknowledged that “Ohio consumers, dairy producers and retailers continue to have differing opinions on its [rbGH] use in the production of milk and milk products.” P.I. App. 0101. Ohio then concluded that it is dairy farmers, and not consumers, who view the labels as potentially implying differences in the milk.” P.I. App. 0101.

28. After the Emergency Rule was issued, the Director held hearings soliciting public comment on the rule. P.I. App. 0111-380.

29. The overwhelming majority of comments submitted to and testimony obtained by ODA opposed the Emergency Rule. Of the approximately 2,700 emails and letters the ODA received in response to the Emergency Rule, less than 70 people commented in favor of the rule.¹ Of the 38 people who testified at the two public hearings (some testified twice), only thirteen supported the rule and of those, three were connected to Monsanto (P.I. App. 0159-65; P.I. App. 0194-98; P.I. App. 0311-18), nine were dairy farmers or relatives thereof (P.I. App. 0138-43; P.I. App. 0149-59; P.I. App. 0193-94; P.I. App. 0232-37; P.I. App. 0250-54; P.I. App. 0280-86; P.I. App. 0293-99; P.I. App. 0357-64.) and one was from the Ohio Farm Bureau. P.I. App. 0237-43.

¹ These numbers are based on the documents provided by ODA, which may include duplicates. Due to time constraints, Plaintiff has made some efforts to remove obvious duplicates but is unable to confirm all duplicates have been removed.

30. The overwhelming majority of consumer comments – in excess of 2,500 – opposed the rule. Consumer Karryn Hart of DeGraff, Ohio wrote: “We do not want ‘rbGH’ in the milk we give our families It’s a safety issue to most of us and a choice we have made.” S.J. App.II 0507. Consumer Megain Coil of Cincinnati, Ohio wrote “Even if rbGH is not harmful to humans, I may wish to avoid it for other reasons. This is my prerogative.” S.J. App.II 0508. Consumer Charles Stevens wrote that he feels the proposed rule “serves to benefit not the consumer, but the profit margin and interests of Monsanto Corporation.” S.J. App.II 0509. In addition to the more than 2,500 consumer comments and testimony opposing the Ohio Rule (e.g. P.I. App. 143-149, 198-210, 305-311, 318-320, 342-357 and 369-373), a number of consumer declarations also opposing the Ohio Rule are attached to this Motion at S.J. App. II 483-506.

31. In expressing support for the rule, some dairy farmers stated: (a) “We have been using the FDA approved product Posilac since its beginning. This product alone makes me an additional \$120,000 annually.” S.J. App.II 0545; (b) “I am from a dairy farm and support the dairy industry and their rights to use technology to remain profitable...” S.J. App.II 0546; (c) “If this food policy counsel is going to have any impact and success, it’s going to have to start protecting technology in agriculture and accept it.” P.I. App. 0141.

32. In the March 12 public hearing, one dairy farmer stated:

ODA’s ruling will benefit the dairy industry in Ohio by creating a level playing field for producers. Currently, dairy producers are not protected from having their product disparaged through labeling, and because the FDA unfortunately chose to leave labeling decisions up to each state, it is vital that ODA step in to protect Ohio’s dairy producers. P.I. App. 0253.

33. Of the consumers who commented in favor of the Emergency Rule, many indicated that they were dairy farmers or relatives of dairy farmers. A selection of such comments are at S.J. App.II 0545-52. Furthermore, a number of the consumer comments in favor of the Emergency Rule were not Ohio residents. A selection of such comments are at S.J. App.II 0553-59.

34. Of the people suggesting they were commenting simply as Ohio consumers, two were found to have ties to Monsanto. Commenter Jesse Armfelt's driver's license address is the same address of Monsanto employee Mark Armfelt. S.J. App.II 0560-66. Additionally, a Patrick J. Haines has a current address the same as the current address of Jesse Armfelt. S.J. App.II 0567-74.

35. Of the remaining individuals suggesting they were commenting as Ohio consumers in favor of the rule, none offered more than their agreement with the Emergency Rule on policy grounds or their belief, as opposed to concrete evidence, that existing labels were misleading.

- a. Ben Hauck, a member of the Ohio Farmers Union, simply claimed the labeling rule is right on the money and did not reference any existing rules. S.J. App.II 0575.
- b. Brenda Price, a former Dairy Producer felt that labels are misleading because there is no difference in milk. S.J. App.II 0576.
- c. Cody W. Stoller, an Ohio veterinarian that serves dairy farms, supported the inclusion of the FDA disclaimer. S.J. App.II 0577.
- d. Mark David Smith, a registered nurse, commented that the rule is fair and honest and easy to comply with. S.J. App.II 0578-79.
- e. Allen Johnson, of Purina Mills, commented that false labels will drive the price up. S.J. App.II 0580.
- f. Andrew Kniesly, of Town & Country Co-op store, stated that it was misleading to claim a product is void of something when it is found no different than other products. S.J. App.II 0581.

36. The Director cited no scientific studies or statistically valid surveys finding evidence that existing labeling was actually deceptive.

37. Neither the Director nor the Governor announced, after a review of the record, that he concluded that existing labeling was actually misleading.

38. Neither the Director nor the Governor announced, after a review of the record, that Ohio consumers, unconnected to Monsanto or dairy farmers, had been actually misled by production claims (as distinguished from absence claims) on labels such as the now banned terms “No rbGH – our cows are not treated with rbGH.”

39. Neither the Director nor the Governor announced, after a review of the record, that Ohio consumers, unconnected to Monsanto or dairy farmers, had been actually misled by labels that include a non-contiguous FDA disclaimer or an FDA disclaimer in a different font, style or color.

40. After the short comment period, on May 22, 2008, the Director in his official capacity, adopted Ohio Administrative Code § 901:11-8-01 (“Ohio Rule”). The effective date of the Ohio Rule was September 19, 2008. The text of the Ohio Rule is substantially the same as the Emergency Rule. P.I. App. 0105-06.

41. In a press release that accompanied issuance of the Ohio Rule the Director described the purpose as ensuring accurate and “balanced information” regarding dairy products. That same representation was made in the minutes of the Joint Committee on Agency Rule Review. P.I. App. 0105; S.J. App.II 0583-90.

42. In a letter to an out-of-state milk processor concluding that that processor’s label is disallowed under the Ohio Rule, the Director described the purpose as ensuring “only the most accurate information” and “that the public has the information necessary to make an informed decision.” P.I. App. 0438.

THE OHIO RULE

43. The Ohio Rule bans certain phrases such as “rbGH Free” or “No rbGH” even if such words are accompanied with production claim language such as “our farmers pledge.” On its face, the Ohio Rule states “[e]xcept as otherwise provided in this rule, accurate production claims will not be deemed false or misleading.” P.I. App. 010.

44. The Ohio Rule requires that the FDA contextual language be in the same font, style and even color as the “permitted claim” (“this milk is from cows not supplemented with rbST” or substantially equivalent claim). The Ohio Rule also prescribes a minimum size of print for the FDA contextual language and requires that this language be at least half the size of the “permitted claim.” The Ohio Rule also imposes a new requirement regarding verification of the non-use of rbGH claim beyond dairy farmer affidavits. P.I. App. 0105-06.

45. Under the Ohio Rule, one is allowed to say “No Artificial Growth Hormone – our farmers pledge,” but not permitted to say “No rbST – our cows are not treated with rbST.” S.J. App.II 0591-92.

46. The Ohio Rule requires a contiguous contextual statement, and thus it inherently prohibits the use of an asterisk or footnote to link the “permitted claim” to the FDA contextual language. P.I. App. 0106. The FDA previously concluded that the use of asterisks is commonly understood by consumers. In an internal memorandum published as a reference to FDA rule-making for dietary supplements and required disclaimer language, the Acting Director, Division of Market Studies of the Department of Health & Human Services concluded, based upon its actual consumer surveys:

The use of asterisks or other symbols to link one statement to another, such as a footnote, is a very common format device that communicates effectively under many circumstances. . . . It is a technique to shorten copy and thereby improve readability. The concern that consumers may fail to recognize the link between the asterisked statement and the disclaimer should be minimal because

this particular device is used in many different contexts and virtually all consumers will be familiar with its use.

Based on the agency's experience . . . , consumers have few problems with this kind of format device.

The memo concludes, "setting any minimum type size always involves tradeoffs between the scarcity of available label space and readability." P.I. App. 0097-98; *see* 62 Fed. Reg. 49859, 49864 (Sept. 23, 1997).

47. Other states with rbGH labeling regulations, including Minnesota, Wisconsin, Vermont, Maine and Alaska, have adopted approaches which expressly permit terms banned in Ohio. P.I. App. 0381-96.

48. The label on Oakhurst dairy products sold in northern New England that reads "Farmers' Pledge: No Artificial Growth Hormone Used" is used and accepted in the states in which it is offered (e.g. Maine, New Hampshire, Massachusetts). The label, however, does not comply with the Ohio Rule because the FDA contextual language, while present, is not contiguous and is not in the same color as the non-use claim. P.I. App. 0419.

THE RULE'S ADVERSE IMPACT ON IDFA'S MEMBERS

49. Dairy products subject to the Ohio Rule are, or were until issuance of the Ohio Rule, produced in Ohio, Arizona, New England, Pennsylvania, Indiana, Minnesota and many other states. P.I. App. 0420-72.

50. A key component of staying competitive is a label that readily conveys an easily recognized and understood message to consumers. P.I. App. 0462, ¶ 6.

51. The implications of a change in the label or removal of the claim entirely could be devastating to a company's sales because consumers may be misled into thinking that there has been a change in policy and the product is now made with milk from rbGH-treated cows. P.I. App. 0463, ¶ 13.

52. The Ohio Rule applies to non-Ohio companies selling dairy products in Ohio even if they are based in another state, have applied for and received approval for their dairy product label in that state and sell their dairy products nationally in a complex warehouse distribution system that prevents distribution variances for products sold in individual states. P.I. App. 0420, ¶ B.

53. Given the structure of the distribution system employed by national customers, Kraft, Tillamook, Hood, Ben & Jerry's, Shamrock and others do not control where particular product will be distributed once delivered to designated distribution points and thus cannot ensure that a product with particular labeling is sent to particular geographic areas. P.I. App. 420-72.

54. One IDFA member quit selling in Ohio products manufactured in Minnesota and labeled in accordance with that state's statute, because it would be commercially impossible to have different labels merely for Ohio. P.I. App. 0429, ¶ 16. The only reason that IDFA member was able to make this particular decision was because it had an alternative non-use claim product that could be sold in Ohio. P.I. App. 0427-30, ¶¶ 7 & 20. This option does not exist for others (e.g. Tillamook or Shamrock) or for other Hood products for which there is no easy substitute. P.I. App. 0452, ¶ 11; P.I. App. 0422-23, ¶ I.3-4.

55. The restrictions of the Ohio Rule are not commercially reasonable, even impossible in some instances, to comply with on smaller containers. P.I. App. 0471, ¶ 16; OTA Add., Ex. C ¶ 26.

56. Under the new Ohio Rule, Reiter Dairy (owned by Dean Foods Company) can no longer use label designs its sister companies use in Pennsylvania. But also, products produced in Pennsylvania that meet Pennsylvania's rules do not meet Ohio Rule provisions. Thus, Dean is faced with a real problem regarding the labels on products produced in Pennsylvania just over the Ohio line in its sister plant in Erie and sold to the same customer base that has stores in both

Pennsylvania and Ohio. Dean's retailers insist on having the same label for their stores whether the milk is purchased in Pennsylvania or Ohio. P.I. App. 0434, ¶ 7.

57. The Director publicly stated "anyone with sales out of Ohio would not need to worry about different label regulation so long as they complied with Ohio's strictest rule." P.I. App. 0472, ¶ 15.

58. The Ohio Rule by its terms and on its face would require most, if not all, existing labels for sale of dairy products in Ohio (and as a practical effect throughout the United States) to be significantly modified to conform with the regimented Ohio Rule even though they are perfectly legal in other jurisdictions. P.I. App. 0106; P.I. App. 0420-72.

59. The Director concluded that the cost of compliance with the Ohio Rule would be minimal (\$250 - \$300 per label type). P.I. App. 0109, ¶ 15.

60. Industry statements actually reveal that costs for complying with Ohio Rule alone would in the tens or hundreds of thousands of dollars and for some, in excess of \$240,000. P.I. App. 0429, ¶ 16; P.I. App. 0445, ¶ 6.51; P.I. App. 0130, 0135-36, 0323-34; P.I. App. 0420-72.

THE RULE'S ADVERSE IMPACT ON OTA'S MEMBERS

61. Some OTA members market and sell their products on a nationwide or regional basis. OTA Add., Ex. A ¶ 3, OTA Add., Ex. B ¶ 3, OTA Add., Ex. C ¶ 4-5. For purposes of maintaining brand recognition and various practical considerations, OTA's national brand members generally use the same labels on virtually all of their milk products. OTA Add., Ex. A ¶ 22; OTA Add., Ex. B ¶ 24.

62. Because the Ohio Rule requires labels different from those that are expressly allowed in other states, OTA's members will be forced to either: (1) create separate Ohio-only labels that will be marketed and sold only in Ohio; (2) change all of their labels nationwide to conform to

the Ohio Rule; or (3) discontinue sales in Ohio altogether. OTA Add., Ex. A ¶ 21; OTA Add., Ex. B ¶ 23; OTA Add., Ex. C ¶ 20.

63. It is not practically or economically feasible for OTA's members to create separate Ohio-only labels that will be marketed and sold only in Ohio. Creating Ohio-only labels would require organic companies to interrupt their manufacturing processes to create new labels for all of their different dairy products and then develop dual systems for labeling, managing and storing products, one for Ohio products and one for products shipped everywhere else. OTA Add., Ex. A ¶¶ 23-24; OTA Add., Ex. B ¶¶ 24-31; OTA Add., Ex. C ¶¶ 21-27.

64. Ohio-only labels will likely cause volatility in the volume available at retail. With a dual system, there may be too little product available in Ohio and no mechanism for shipping products sold in neighboring states to replenish the supplies in Ohio. If organic dairy producers increase their volume of uniquely labeled products and there is insufficient demand in Ohio, they will face the opposite problem because dairy products are perishable and cannot be maintained for long periods of time. OTA Add., Ex. A ¶ 28.

65. Many major supermarkets who purchase organic dairy products from OTA's members utilize warehouse and distribution systems that cut across state lines. Unique Ohio-only labels will result in substantial increases in the complexity and costs for the major supermarket's warehouse and distribution systems because they will have to create a dual system, one for Ohio-based products and one for products that can be shipped elsewhere. OTA Add., Ex. A ¶¶ 31-34; OTA Add., Ex. B ¶¶ 27-28; OTA Add., Ex. C ¶ 24.

66. Organic dairy companies, moreover, will not have any way to ensure that products, once they leave the companies' distribution centers, actually end up in a particular state. The organic dairy companies would be forced to rely on the storage and distribution facilities of major

supermarket chains to ensure that products without the Ohio-only labels do not get sold in Ohio.

OTA Add., Ex. A ¶¶ 31-34; OTA Add., Ex. B ¶¶ 27-28; OTA Add., Ex. C ¶ 24.

67. The estimated costs associated with changing product labels ranges from \$130,000 to \$240,000 and possibly more, as those estimates do not take into account artwork costs, labor costs of a branding team and other costs relating to the labeling process. OTA Add., Ex. A ¶ 29; OTA Add., Ex. B ¶ 31; OTA Add., Ex. C ¶ 21. It also does not include the substantial increase in costs associated with the dual storage and distribution systems. OTA Add., Ex. A ¶ 29.

CONSUMER DEMAND FOR ORGANIC DAIRY PRODUCTS

68. Consumer demand for organic products has increased significantly over the last 20 years. Consumers of organic food generally want their food to be free of artificial growth hormones as well as antibiotics and toxic pesticides. OTA Add., Ex. A ¶ 14; OTA Add., Ex. F.

69. A 2006 survey commissioned by the USDA also indicates that consumers want to know whether the cattle are fed organic feed (*e.g.* without pesticides) and whether antibiotics are used in the raising of the livestock. *Id.*

70. Many OTA members voluntarily label their products with messages to indicate that their products are made without the use of antibiotics and toxic pesticides. OTA Add., Ex. A ¶ 17; OTA Add., Ex. B ¶ 20; OTA Add., Ex. C ¶ 16.

71. All certified organic dairy processors, including many of OTA's members, must comply with the Organic Foods Production Act, and its implementing regulations, the National Organic Program (collectively referred to herein as "OFPA"). OFPA forbids the use of antibiotics, growth promoting or production increasing hormones (including rbST) and toxic and persistent pesticides on pastures and crops grown to feed cows. OTA Add., Ex. A ¶¶ 6, 9, OTA Add., Ex. B ¶ 11, OTA Add., Ex. C ¶¶ 7-11, 13.

72. In order to market their products as “organic,” certified organic farmers must, among other things, establish an organic plan, engage in rigorous recordkeeping, submit to an annual on-site inspection of their farms by a USDA accredited certifying agent, and follow the National Organic Program standards regarding all operations of their farms. OTA Add., Ex. A ¶¶ 7-11; OTA Add., Ex. B ¶¶ 9-11; OTA Add., Ex. C ¶¶ 7-11.

Respectfully submitted,

/s/ John C. McDonald

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CERTIFICATE OF SERVICE

I certify that a copy of the foregoing has been filed electronically on this 25th day of July, 2008.

/s/ John C. McDonald
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